

REMARKS

The undersigned appreciate and thank Primary Examiner Leffers for his helpful comments during their recent discussion of the application. Further to that discussion, the claims have been amended as discussed during the interview and as further discussed below. Claims 32 and 37 were amended and new claims 47-60 added to recite the cellular phenotypes which are compared in the methods.

Claims 32-46 are presently pending in the application. Claims 32, 37 and 46 have been amended and claims 47-60 have been added. No new matter has been added by virtue of the amendments. For instance, support for the amendments of claims 32 and 37 and new claims 47-60 appears e.g. at least at page 9, lines 18-24. No new matter has been added. The amendment of claim 46 is merely to address a matter of form.

Claims 37-42 were objected to under 37 C.F.R. § 1.75 as being substantial duplicates of claims 32-36. The rejection is traversed.

Section 706.03(k) of the MPEP states, "court decisions have confirmed applicant's right to restate (i.e., by plural claiming) the invention in a reasonable number of ways. Indeed, a mere difference in scope between claims has been held to be enough." Claims 37-42 are not substantial duplicates of claims 32-36, but instead are claims of different scope. Said in another way, claims 37-42 are directed to different aspects of the invention than are claims 32-36. One aspect is predicting of the pharmacological effect a drug candidate compound would have on a cell and the other is identifying a protein as a potential drug target. The methods may have common steps, but they are different in scope and substantive content because they are directed at different aspects of the invention. Thus, the claims are not substantial duplicates of each other. Accordingly, withdrawal of the objection is requested.

Claims 32-46 were rejected under 35 U.S.C. § 112, second paragraph, as being indefinite. The rejection is respectfully traversed.

As stated above, claims 32 and 37 are directed to different aspects of the invention. One aspect is predicting of the pharmacological effect a drug candidate compound would have on a cell and the other is identifying a protein as a potential drug target. The methods may have common steps, but they are not unclear to one of skill in the art because both methods would be evident to the skilled artisan from Applicant's disclosure. The claims are thus clear as written and do not need any additional steps to achieve the stated outcomes.

The Office Action further asserts that Claim 32 is unclear because there is "no explicit linkage between the candidate test compound and the targeted protein." The claim explicitly recites, "a difference in phenotype between the host cells in which expression of the protein has been modulated and the phenotype of control host cells in which expression of the protein has not been modulated predicts the pharmacological effect a drug candidate compound would have in a cell, tissue, or organ that expresses the protein." This is an explicit linkage, i.e., the drug candidate compound's effect is predicted by the difference in the phenotype of the cells. The amendment suggested by the Examiner would unduly limit the claims because the drug candidate may not affect the functional activity of the protein that is modulated, but may affect the activity of a protein which interacts with the modulated protein, which in turn affects the activity of the modulated protein or may affect the downstream proteins of the modulated protein, etc. Thus, the claim is clear as written and provides an explicit link between the "the candidate test compound and the targeted protein."

The Office Action further asserts that claim 46 is unclear because it does not set forth any steps and because it is unclear what constitutes a "standard" drug discovery strategy. The former is discussed below. As for the latter rejection, claim 46 was amended merely to clarify the claim to recite "traditional drug discovery strategy." Examples of traditional drug discovery strategies are found throughout the specification.

In view thereof, reconsideration and withdrawal of the rejection are requested.

Claim 46 was also rejected under 35 U.S.C. § 101 for being directed at non-statutory subject matter on the grounds that the claim does not recite proper method steps. The rejection is traversed.

To expedite prosecution, and in no way acquiescing to the rejection, claim 46 was amended without substantive limitation to obviate the rejection to recite, “further comprising screening the potential drug target protein in a traditional drug discovery strategy.” Withdrawal of the rejection is requested.

Claims 32-46 were rejected under 35 U.S.C. § 102(e) over Lamb (U.S. Patent No. 5,955,275). The Examiner has maintained the rejections of the previous office action. The rejection is traversed.

As discussed with Examiner Leffers, nowhere does Kamb teach or suggest, “comparing the phenotype of the host cells in which expression of the protein has been modulated to the phenotype of control host cells in which expression of the protein has not been modulated... wherein the phenotype is propagation of an electrical charge, growth, blebbing or budding, pycnotic transformation, kinesis, cell death, differentiation, replication, transcription, translation, protein processing, adhesion, oncogenetic transformation, enzymatic catalysis, or protein modification.”

Rather, Kamb reports certain use of a certain reporter gene as a surrogate for the pheontype of a cell. See Col. 3, lines 5–31 of the Kamb document.

That report an in no way be interpreted to anticipate Applicant’s methods, which directly compare the cellular phenotype and do not rely on a reporter gene as a surrogate. Kamb’s surrogate is not a comparison of propagation of an electrical charge, growth, blebbing or budding, pycnotic transformation, kinesis, cell death, differentiation, replication, transcription, translation, protein processing, adhesion, oncogenetic transformation, enzymatic catalysis, or protein modification.

The Examiner's admission of Kamb's teaching of the use of a **reporter protein** serves to make Applicant's point that Kamb does not teach or suggest "comparing the phenotype of the host cells in which expression of the protein has been modulated to the phenotype of control host cells in which expression of the protein has not been modulated ... wherein the phenotype is propagation of an electrical charge, growth, blebbing or budding, pycnotic transformation, kinesis, cell death, differentiation, replication, transcription, translation, protein processing, adhesion, oncogenetic transformation, enzymatic catalysis, or protein modification."

Kamb does not, therefore, teach each and every element of Applicant's claims and the rejection is properly withdrawn. In this regard, attention is directed to Section 2131 of the Manual of Patent Examining Procedure, which states in part:

A claim is anticipated only if and each and every element as set forth in the claim is found, either expressly or inherently described in a single prior art reference." * * * The identical invention must be shown in as complete detail as is contained in the .. claim."

In view thereof, reconsideration and withdrawal of the rejection is requested.

It is believed the application is in condition for immediate allowance, which action is earnestly solicited.

Respectfully submitted,



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Date: July 29, 2004

Customer No.: 21874